K101555

SEP 17 2010

Section III. 510(k) summary

eBeam CO_2 Laser System

Advanced Technology Laser Co., Ltd

(As required by 21 CFR 807.92)

1. Date Prepared: March 22, 2010

2. Sponsor Information

Advanced Technology Laser Co., Ltd
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Shanghai, 200240, China

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3. Submission Correspondent

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4. Proposed Device Information

Device Common or Usual Name: Carbon dioxide laser;
Device Trade or Proprietary Name: eBeam CO_2 Laser System
Model: eBeam
Classification Name: Laser instrument, Surgical, Powered
Regulation Number: 21 CFR 878.4810
Product Code: GEX
Panel: 878 General and Plastic Surgery

5. Predicate Device

SLIM Evolution Family of CO_2 Laser and Delivery Device Accessories (K063001)

6. Device Description

eBeam CO_2 Laser System is an intelligent sealed-off CO_2 laser. eBeam CO_2 Laser System delivers laser energy to the treatment site via a 7-joint spring-balanced articulated arm in which mirrors reflect the laser beam along the axis of arms to enter the output device- the specially designed handpiece.

eBeam CO_2 Laser System can produce a laser beam with a wavelength of 10.6 μ m which is effective on all soft tissues, thus it can be used in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic(dermatology and plastic surgery), general surgery, gynecology, podiatry, dental and otorhinolaryngology.

eBeam CO_2 Laser System consists of control system, user interface, power supply, laser emission and delivery system, cooling system, safety features and handpieces (including scanning handpiece and normal handpiece).

7. Intended use

eBeam CO_2 Laser System is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), general surgery, gynecology, podiatry, dental and otorhinolaryngology.

8. Substantial Equivalence

eBeam CO_2 Laser System shares the same indications for use and safety compliance, similar design features, functional features, and therefore are substantially equivalent to the predicate device, SLIM Evolution Family of CO_2 Lasers and Delivery Device Accessories (K063001). In addition, a review of the predicate device demonstrate that eBeam CO_2 Laser System is safe and effective as the predicate device as they share equivalent wavelengths, and are used to perform the same indicated surgical procedures. Therefore the proposed device is substantially equivalent (SE) to the predicate device.

9. Testing

eBeam CO_2 Laser System is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-22: 2007, Medical Electrical Equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part1: General requirements for safety.
- IEC60601-1-2:2001+A1:2004, Medical Electrical Equipment – Part 1: General requirements for safety-2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

The devices also comply with European Medical Directive 93/42/EEC and the US Federal Performance Standards 21 CFR 1002.10 Requirements (21CFR 1040.10 and 21CFR 1040.11 for Class IV Laser Products), Part 820 – Quality System Regulation, and have passed ISO9001 and ISO13485 System Certification.

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verify that the proposed device, eBeam CO_2 Laser System met all design specifications and was substantially equivalent to the predicate device.

Clinical Conclusion: No Clinical Information is required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Technology Laser Co., Ltd.
% Underwriters Laboratories, Inc.
Laboratory and Testing
Mr. Marc M. Mouser
2600 N.W. Lake Road
Camas, Washington 98607-9526

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Re: K101555
Trade/Device Name: eBeam CO_2 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 08, 2010
Received: September 09, 2010

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Dep Dir

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101555

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Attachment IV Indications for Use Statement

510(k) Number: K101555

Device Name: eBeam CO_2 Laser System

Indications for Use:

eBeam CO_2 Laser System are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), general surgery ,gynecology,podiary,dental and otorhinolaryngology

Dermatology, Plastic Surgery and General Surgery procedures including but not limited to:

Laser skin resurfacing
Treatment of furrows and wrinkles
Removal of skin tags, actinic keratosis, acne scars, keloids, tattoos, telangiectasia, squamous and basel cell carcinoma, warts and uneven pigmentation.
Treatment of cysts, abscesses, hemorrhoids and other soft tissue applications.
Blepharoplasty
Site preparation for hair transplants

Dental procedure including but not limited to -

Periodontal procedures such as - gingivectomy, removal of hyperplasias , gingivoplasty (incision and excision);
Oral Surgery procedures such as - aphous ulcer excision, frenectomy, benign /malignant lesion ablation, operculectomy and homeostasis

Prescription Use X **AND/OR** **Over-The-Counter Use**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Podiatry procedures including but not limited to -

Ablation, vaporization and excision of soft tissue lesions such as ingrown nail, fungal nail, porokeratoma, matrixectomy and verrucae vulgares.

Otorhinolaryngology (ENT) procedures including but not limited to -

Treatment of leukoplakia of larynx, nasal obstruction, rhinophyma, verrucrea vulgares, choanal atresia, rhinophyma, LAUP and papillomatosis polyps.

Gynecology

Treatment of condyloma acuminata, cervical intraepithelial neoplasia, leukoplakia and vulvar/vaginal intraepithelial neoplasia, cervical dysplasia.

This device is for prescription use only.

The safety and effectiveness of this scanner/device has not been evaluated as a fractionated scanner/device.

Prescription Use X **AND/OR** **Over-The-Counter Use**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**
(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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